JUL 17 2009

Summary of Safety and Effectiveness: Philips CX50 2.0 K091804

The submitter of this premarket notification is:
Rob Butler
Manager, Regulatory Affairs
Philips Ultrasound, Inc.
3000 Minuteman Road
Andover, MA 01810-6302
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This summary was prepared on June 17, 2009.

The proprietary name of the device is the CX50 Diagnostic Ultrasound System. In combination with its compatible transducers, the system is commonly known as a diagnostic ultrasound system and transducers.

These devices are classified as follows:

90IYN	Ultrasonic Pulsed Doppler Imaging System
90IYO	Ultrasonic Pulsed Echo Imaging System
90ITX	Diagnostic Ultrasound Transducer

As stated in 21 CFR, parts 892.1550, 892.1560 and 892.1570, each of these generic types of devices have been classified as Class II.

CX50 2.0 is a modification of the CX50 (1.0) compact diagnostic ultrasound system cleared for Philips Ultrasound in K081802. The 2.0 modification adds 4 additional transducers for use with the CX50 system; these transducers and software changes in release 2.0 enable expanded intended uses for the CX50 system. These expanded intended uses are all within the cleared intended uses for the predicate device, Philips iU22 diagnostic ultrasound system (cleared in K030455), to which CX50 2.0 is substantially equivalent.

CX50 2.0 is intended for diagnostic ultrasound imaging and fluid flow analysis.

CX50 2.0 is substantially equivalent in safety and effectiveness to the predicate identified above:

- Both the predicate device and CX50 2.0 are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- Both the predicate device and CX50 2.0 have the same gray-scale and Doppler capabilities.
- Both the predicate device and CX50 2.0 use essentially the same technologies for imaging, Doppler functions and signal processing.

- Both the predicate device and CX50 2.0 have acoustic output levels below the Track 3 FDA limits.
- Both the predicate device and CX50 2.0 are manufactured under equivalent quality systems.
- Both the predicate device and CX50 2.0 are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- Both the predicate device and CX50 2.0 are designed and manufactured to the same electrical and physical safety standards.

Introduction

This 510(k) premarket notification submission has been prepared in adherence with the FDA guidance; Information for Manufactures Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, issued on September 9, 2008.

Basic Information

Manufacturer's Name

Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA 98021-8431

Corresponding Official for this submission
Rob Butler
3000 Minuteman Rd
Andover, MA 01810
Phone (978) 659-2785
Fax (978) 975-7234

Initial distributor:

Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA 98021-8431

Device Name

CX50 Diagnostic Ultrasound System. This submission covers the 2.0 release of CX50.

Common Name:

Diagnostic Ultrasound System and Transducers

Classification

Regulatory Class: II
Review Category: Tier II
Review Panel: Radiology

Device Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Establishment Registration Number

Philips Ultrasound, Inc. 1217116

514 Performance Standards

There are no Sec. 514 performance standards for this device.

Prescription Status

This is a prescription device. The prescription device statement appears in the labeling.

Manufacturing Location

Philips Ultrasound
22100 Bothell Everett Highway
Bothell, WA 98021-8431

Sterilization Site(s)

Not applicable. No components supplied sterile.

Reason for Submission

The contents of this submission describe the 2.0 release of CX50 – modifications to the CX50 (1.0 release) system previously cleared in K081802. The changes include:

- Adding to CX50 indications for use and features that are already cleared for use on the predicate device (Philips iU22 ultrasound system – K030455)
- Adding 4 transducers to CX50; 2 have been previously cleared on other Philips ultrasound systems; 2 are minor modifications of previously cleared transducers
- Adding "Integrated Ultrasound" capability, which facilitates workflow between the CX50 and the Philips Allura Xper X-ray system (K041949).

Track

This is a Track 3 system.

Indications for Use

The CX50 2.0 Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following clinical applications: Cardiac (adult), Ophthalmic, Fetal, Abdominal, Pediatric, Musculoskeletal, Peripheral Vessel, Small Organ, Trans-vaginal, Adult Cephalic, and Gynecological.

The clinical environments where the CX50 Diagnostic Ultrasound System can be used include point-of-care areas in offices, clinical and hospital settings for diagnosis of patients.

These use models are within the scope of and substantially equivalent to current indications for use for Diagnostic Ultrasound System.

The 510(k) Indications for Use forms on the following 6 pages show previously cleared indications for use for the CX50 (1.0 release) system and indications for use added with this 2.0 release of CX50. The CX50 2.0 release made no changes to the indications for use for the X7-2t and D2cwc transducers as cleared on K081802, so no Indications for Use form is provided for those two transducers. The CX50 2.0 release does add indications for use for the S5-1 transducer from what was cleared on K081802, so an Indication for Use form for S5-1 is included in this submission, showing both previously cleared and new (with CX50 2.0) indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2009

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091804
Trade/Device Name: CX50 2.0 Diagnostic Ultrasound System and Transducers
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 3, 2009
Received: July 6, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the CX50 2.0 Diagnostic Ultrasound System and Transducers, as described in your premarket notification:

Transducer Model Number

S5-1
L12-3
C9-3v
C5-1
D5cwc

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

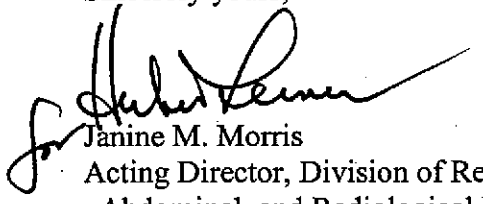
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact William C. Jung at (240) 276-3666.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K091804

Device Name: CX50 2.0 Diagnostic Ultrasound System and Transducers

Indications for Use:

Cardiac (Adult, Trans-esophageal) (previously cleared in K081802)

Applications added in CX50 2.0:

- Ophthalmic
- Fetal
- Abdominal
- Pediatric
- Musculoskeletal
- Peripheral Vessel
- Small Organ
- Trans-vaginal
- Adult Cephalic
- Gynecological

"Integrated Ultrasound" - capable of facilitating work flow between CX50 and Philips Allura Xper X-ray system (K041949)

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091804

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K091804

Device name: CX50 2.0 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic	N	N	N		N	N	N (1,4,6,7)
Fetal Imaging & Other	Fetal/Obstetric	N	N	N	N	N	N	N (1,3-8)
	Abdominal	N	N	N	N	N	N	N (1,3-9)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N (1,3-8)
	Small Organ (thyroid, scrotum, prostate, breast)	N	N	N		N	N	N (1,3-8)
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	N	N (1,3-7)
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	N (1,3-8)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	N	N	N		N	N	N (1,3-8)
	Musculo-skel (superficial)	N	N	N		N	N	N (1,3-8)
	Other (Gynecological)	N	N	N		N	N	N (1,3-9)
Cardiac	Cardiac Adult	P	P	P	P	P	P	P(1-4)
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P(1-4)
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	N	N (1,3-8)
	Other (Carotid)	N	N	N		N	N	N (1,3-8)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue or Contrast)	6. 3D (Freedhand) Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K081802 for first release of CX50	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091804

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K091804

Device name: S5-1 transducer for use with CX50 2.0 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic	N	N	N		N	N	N (1,4,6,7)
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	N	N	N		N	N	N (1,3-8)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	N	N (1,3-7)
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes:	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D (Freedhand) Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission: K081802 – use of S5-1 transducer with first release of CX50	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091804

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K091804

Device name: L12-3 transducer for use with CX50 2.0 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal	N	N	N		N	N	N (1,3-8)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N (1,3-8)
	Small Organ (thyroid, scrotum, prostate, breast)	N	N	N		N	N	N (1,3-8)
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)	N	N	N		N	N	N (1,3-8)
	Musculo-skel (superficial)	N	N	N		N	N	N (1,3-8)
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N (1,3-8)
	Other (Carotid)	N	N	N		N	N	N (1,3-8)

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D (Freedhand) Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091804

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K091804

Device name: C9-3v transducer for use with CX50 2.0 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N		N	N	N (1,3-8)
	Abdominal	N	N	N		N	N	N (1,3-9)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	N (1,3-9)
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)	N	N	N		N	N	N (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

*Other modes:	
1. Harmonics (Tissue & Contrast)	5. Angio Imaging
2. Tissue Doppler Imaging	6. 3D (Freedhand) Imaging
3. iSCAN	7. SonoCT
4. X-Res	8. Biopsy guidance
	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091804

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K091804

Device name: C5-1 transducer for use with CX50 2.0 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric	N	N	N		N	N	N (1,3-8)
	Abdominal	N	N	N		N	N	N (1,3-9)
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N (1,3-9)
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)	N	N	N		N	N	N (1,3-8)
	Other (Gynecological)	N	N	N		N	N	N (1,3-9)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	N (1,3-8)
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D (Freedhand) Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091804

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) Number: K091804

Device name: D5cwc transducer for use with CX50 2.0 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify) See below	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal/Obstetric							
	Abdominal							
	Intra-operative (vascular/epicardial)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (thyroid, scrotum, prostate, breast)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
	Other (Gynecological)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Fetal)							
Peripheral Vessel	Peripheral vessel				N			
	Other (Carotid)				N			

N= new indication; P= previously cleared by FDA; E= added under Appendix E

***Other modes:**	5. Angio Imaging
1. Harmonics (Tissue & Contrast)	6. 3D (Freedhand) Imaging
2. Tissue Doppler Imaging	7. SonoCT
3. iSCAN	8. Biopsy guidance
4. X-Res	9. Infertility monitoring of follicle development
Combined modes: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	
Previous submission:	

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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091804